NO. 14-1034

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

THERMOLIFE INTERNATIONAL LLC

Plaintiff-Appellee,

v.

LECHEEK LLC, ET AL.

Defendants-Appellants.

Appeal from the United States District Court for the Central District of California in Case No. 12-cv-09229 GAF (FFMx), Judge Gary A. Feess

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DEFENDANTS-APPELLANTS LECHEEK LLC, LONE STAR DISTRIBUTION, MAXIMUM HUMAN PERFORMANCE, LLP, PURUS LABS, INC., REACTION NUTRITION, LLC, REDEFINE NUTRITION, LLC; NUTRAPLANET; BIO-ENGINEERED SUPPLEMENTS AND NUTRITION, INC.; BRONSON LABORATORIES, INC.; GNC CORPORATION; GENERAL NUTRITION CENTERS, INC.; GENERAL NUTRITION CORPORATION; PHARMAFREAK HOLDINGS, INC., SNI LLC; MUSCLE WARFARE, INC.; AND NUTREX RESEARCH, INC.'S OPENING BRIEF

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Form 9

FORM 9. Certificate of Interest

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Thermolife International LLC v. Lecheek LLC, et al.

No. 14-1034

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party) appellants certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Lecheek LLC; Lone Star Distribution; Maximum Human Performance, LLP; Purus Labs, Inc.; Reaction Nutrition, LLC; Redefine Nutrition LLC; and NutraPlanet.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

John's Lone Star Distribution, Inc. is doing business as Lone Star Distribution.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None.

4. ☐ The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

William J. Cass, Jeffery B. Arnold, Keith J. Murphy and Andrew C. Ryan, all of the law firm of Cantor Colburn, LLP; and Daniel S. Silverman of the law firm Venable LLP.

11/1/13
Date

Signature of counsel

William J. Cass
Printed name of counsel

Please Note: All questions must be answered
cc: All counsel representing the parties of record

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

THERMOLIFE INTERNATIONAL, LLC v. LECHEEK LLC, et al.

No. 14-1034

CERTIFICATE OF INTEREST

Counsel for the appellants,
certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:
Bio-Engineered Supplements and Nutrition, Inc.; Bronson Laboratories, Inc.; GNC Corporation; General Nutrition Centers, Inc.; General Nutrition Corporation; and PharmaFreak Holdings, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:
Same as listed above.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:
The parent company of Bio-Engineered Supplements and Nutrition, Inc. ("BSN") is Glanbia, Inc. No publicly held corporation owns 10% or more of BSN's stock. GNC Holdings, Inc., is GNC's parent corporation. No publicly held corporation owns more than 10% of GNC's stock. Bronson Laboratories, Inc. has no parent corporation and no publicly held corporation owns 10% or more of its stock. The parent corporation of PharmaFreak Holdings, Inc. is PharmaFreak SG, Inc. No publicly held corporation owns 10% or more of their stock.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:
Daniel S. Silverman of the law firm Venable LLP.

November 8, 2013
Date


Signature of counsel

Daniel S. Silverman (SBN 137864)
Printed name of counsel

Please Note: All questions must be answered
cc: _____

Effective May 1, 2008

Form 9

FORM 9. Certificate of Interest

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Thermolife International llC v. Lecheek LLC, et al.

No. 14-1034

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party) Nutrex Research, Inc. certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Nutrex Research, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Not applicable.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None.

4. ☑ The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Ryan T. Santurri, Stephen H. Luther, Ava K. Doppelt, all of the Law Firm of Allen, Dyer, Doppelt, Milbrath & Gilchrist, P.A.

11/12/2013
Date

Signature of counsel

Ryan T. Santurri
Printed name of counsel

Please Note: All questions must be answered
cc: All counsel representing the parties of record

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Thermolife International LLC v. LeCheek, LLC et al.

CASE NO. 14-1034

CERTIFICATE OF INTEREST

Counsel for Appellant, SNI, LLC, certifies the following:

1. The full name of every party or amicus represented by me is:

SNI, LLC

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

SNI, LLC

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

SNI, LLC

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

William E. Thomson
Rolando J. Tong
Brooks Kushman P.C.

Date: November 13, 2013

/s/ William Thomson

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Form 9

FORM 9. Certificate of Interest

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ThermoLife International LLC v. Lecheek LLC et al.

No. 14-1034

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party) Appellant certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Muscle Warfare, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Same as party.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None.

4. ☑ The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Derek Newman, Newman Du Wors LLP

11/5/13
Date

Signature of counsel

Keith Scully
Printed name of counsel

Please Note: All questions must be answered

cc:

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STATEMENT OF RELATED CASES

To counsels' knowledge, there are no other related cases or proceedings that are presently before any other court or agency, state or federal.

STATEMENT OF JURISDICTION

This is a patent infringement action pursuant to Title 35 of the Patent Laws. The patent at issue is U.S. Patent No. 8,202,908, entitled, "*D-Aspartic Acid Supplement"* (hereinafter the " '908 Patent").

The Complaint alleged subject matter jurisdiction under 35 U.S.C. §§ 1331, 1338 and 1367. The district court held the '908 Patent invalid. This appeal concerns the denial of an award of attorneys' fees for the Defendants. This Court has exclusive jurisdiction over an appeal from the denial of an award for attorneys' fees in a patent infringement action pursuant to 28 U.S.C. § 1295.

STATEMENT OF THE ISSUES PRESENTED

1. Whether the court erred as a matter of law when it failed to award Defendants' attorneys' fees where Plaintiff Thermolife International LLC ("Thermolife"): (a) received prompt notice that the '908 Patent was invalid in light of prior art; (b) failed to investigate the validity of the asserted patent, and continued to prosecute this action; (c) failed to undertake a claim construction analysis of the asserted claims prior to commencing the lawsuit; and (d) argued several claim interpretations that are plainly contrary to longstanding precedent in an effort, albeit unsuccessfully, to oppose summary judgment.

2. Whether the court erred as a matter of law when it failed to entertain the Defendants' Motion under Rule 11, Fed. R. Civ. P.

STATEMENT OF THE CASE

A. Nature of the Case

Thermolife commenced this patent infringement action on October 26, 2012, for the alleged infringement of the '908 Patent. A99-A140. The '908 Patent claims priority to a Provisional Patent Application filed on March 28, 2008. A993-A996 and A1865-A1881. The '908 Patent claims a method, *inter alia*, of increasing testosterone levels in males by the oral administration of D-aspartic acid. A993-A996.

The '908 Patent is anticipated under 35 U.S.C. § 102(b) by Italian Patent Application IT2005RM0468A1 (the "Italian Patent Application"), which describes the oral administration of D-aspartic acid to increase male testosterone levels in the blood, and was publicly available on March 15, 2007. A25-A40; A41-A43, A993-A996; A1364-A1370 at A1366, ¶6 and ¶9; A1539-A1607; and A1620-A1659; and A1865-A1881. The publication of the Italian Patent Application was disclosed to Thermolife on December 21, 2012, shortly after this lawsuit was filed. A1672-A1766.

In response, Thermolife made the false assertion that the Italian application was not a "printed publication" or capable of being so under 35 U.S.C. § 102(b) in

2007. Thermolife also filed meritless validity contentions and suggested that an expert would demonstrate at trial that the application does not describe the invention. A1768-A1769; A1843-A1844; and A4188-A4199.

On July 15, 2013, Defendants moved for summary judgment of invalidity based on the Italian Patent Application and other prior art. A1290-A1329; A1330-A1363; A1364-A1990; and A3458-A3530. Defendants also moved for attorneys' fees under 35 U.S.C. § 285 on the grounds that Thermolife failed to investigate the validity of the patent, failed to consider a construction of the patent claims before the lawsuit was filed, and continued to pursue this case even though it was presented with invalidating prior art shortly after the case was filed, and long before Defendants' Summary Judgment Motion was filed. A1290-A1329 at A1304, lns. 8-26; A1672-A1766; A1835-A1841; and A1771-A1776. Defendants also filed a Motion under Rule 11 of the Federal Rules of Civil Procedure ("Rule 11 Motion") at the same time as they filed their Summary Judgment Motion. A2068-A2107; A2108-A2739; A2740-A2815; and A2821-A2825. Defendant Muscle Warfare, Inc. also filed its Motion for Sanctions on June 25, 2013. A1006-A1030; A1031-A1043; A1044-A1200. The Rule 11 Motions were stricken as premature. A2828-A2829.

Additionally, in an effort to oppose summary judgment, Thermolife argued several claim interpretations that are opposite to longstanding precedent. A2912-

A2936 at A2919, ln. 6 - A2932, ln. 21. For example, the two claims of the '908 Patent include the Markush format. Thermolife argued that the prior art must include **each member** of the Markush group to anticipate the claim, which is plainly contrary to long standing precedent on the legal construction of Markush claims. A2912-A2936 at A2926, ln. 9-A2928, ln. 5; A2937-2974 at A2956, ¶59, A2957 at ¶62, A2961-A2962 at ¶67; and A3136-A3226 at A3139-A3143, ¶¶ 11-24. Thermolife also argued that a **single data point** within a claimed range did **not** anticipate the claimed range, which also is contrary to longstanding precedent. A2912-A2936 at A2931, lns. 16-19; A3136-A3226 at A3147, ¶ 33; and A3531-A3553 at A3537, lns. 16-23.

On October 8, 2013, the district court granted Defendants' Motion for Summary Judgment of Invalidity, holding the '908 Patent invalid based on the Italian Patent Application. The district court denied Defendants' request for attorneys' fees. A25-A40 and A41-A43. The district court improperly reasoned that attorneys' fees were not warranted in part because Thermolife had retained an expert, even though the expert's opinion was based on Thermolife's flawed interpretation of the claims. A25-A40 and A41-A43; A3136-A3226.

The Defendants appeal from that portion of the Order of October 8, 2013 denying the request for attorneys' fees and the court's failure to consider Defendant's Rule 11 Motion. A25-A40 and A41-A43; A3953-A3959.

B. Procedural History

Thermolife commenced this patent infringement action on October 26, 2012. A99-A140. On January 25, 2013, the district court entered an Order to Show Cause as to why joinder of all of the Defendants was proper under the American Invents Act of 2011. A44-A98 at A78 [Dkt. No. 119]. On February 13, 2013, the court ordered that the action be dismissed and re-filed (except as to the lead case). A44-A98 at A80 [Dkt. No. 131]. On March 6, 2013, the district court issued a Civil Minute Order determining that some consolidation was appropriate to achieve judicial economy and ordered the parties to submit a case management report. A876-A878. On March 21, 2013, the parties submitted a case management report. A44-A98 at A81 [Dkt. No. 145].

At the first Scheduling Conference held on May 6, 2013, Thermolife represented that it would object to the English translation of the Italian Patent Application. Thermolife further represented that it had **not** undertaken a construction of the asserted patent claims. The court ordered the parties to meet and confer and file a detailed Joint Statement, setting forth their respective positions as they pertain to Inter Partes Review, and to file their Validity Contentions no later than May 13, 2013. The court also ordered Thermolife to file any objections to the translation of the Italian Patent Application by May 13, 2013. A44-A98 at A85 [Dkt. No. 184].

On May 13, 2013, the parties filed their respective Validity Contentions, and Thermolife filed a notice of non-objection to the translation of the Italian Patent Application. A4188-A4199. On May 22, 2013, the court held a second Scheduling Conference and ordered the parties to submit a briefing schedule for summary judgment on the issue of validity. A44-A98 at A87 [Dkt. No. 197] and A1818-A1830.

On July 15, 2013, the Defendants moved for summary judgment of invalidity based on the Italian Patent Application and other prior art and requested their attorneys' fees. The Defendants moved for attorneys' fees under 35 U.S.C. § 285 on the grounds that Thermolife failed to investigate the validity of the patent and to consider a construction of the patent claims before the lawsuit was filed, and continued to pursue this case even though it was presented with invalidating prior art shortly after the case was filed. The Defendants also filed a Motion under Rule 11 of the Federal Rules of Civil Procedure (which was stricken as premature). A44-A98 at A88-A91 [Dkt. Nos. 204, 214-215, and 220].

On August 5, 2013, Thermolife filed its Opposition to Defendants' Motion for Summary Judgment. In its Opposition, Thermolife argued several claim interpretations that are simply wrong. Thermolife argued that the prior art must include each member of the Markush group to anticipate the claim, which is plainly contrary to long standing precedent on the legal construction of Markush

claims. Thermolife also argued that a single data point within a claimed range did not anticipate the claimed range which also is contrary to longstanding precedent. A2912-A2936 at A2926, ln. 9-A2928, ln. 5 and A2931, lns. 16-19; A2937-2974 at A2956, ¶59, A2957 at ¶62 and A2961-A2962 at ¶67; A3136-A3226 at A3139-A3143, ¶¶ 11-24; A3147, ¶ 33; and A3531-A3553 at A3537, lns. 16-23.

Included with its Opposition and in further support of its arguments, were the Expert Declarations of Manfred E. Wolff, Ph.D. ("Dr. Wolff") and Guido Moradei ("Mr. Moradei"). A2983-A3135 and A3136-A3226. Also included with the Opposition was a Declaration of the inventor identifying an uncorroborated and a redacted e-mail he allegedly sent to his attorney attempting to establish a date of invention earlier than January 2, 2008. A2975-A2982.

On August 16, 2013, the Defendants filed their Reply to Thermolife's Opposition to the Motion for Summary Judgment. A3531-A3553. Defendants also filed Evidentiary Objections to the Declarations of Dr. Wolff and Mr. Moradei, on the grounds that the Expert Declarations were based on Thermolife's flawed claim interpretation and/or otherwise should be disqualified under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). A3554-A3604. The Defendants also objected to the Declaration of the inventor on the basis that the redacted document could not be used as both a sword and a shield. A3531-A3553 at A3547, lns. 1-17.

On August 22, 2013, the district court entered a Civil Minute Order that Defendants file a copy of an unpublished study referenced in the Italian Patent Application and that Thermolife file an un-redacted copy of the e-mail sent by the inventor to his attorney. A3605. On August 27, 2013, Thermolife filed an application to file the inventor's e-mail to his attorney for an *In Camera* Review, which was granted. A3612-A3624. On August 30, 2013, the Defendants filed a Supplement to their Motion appending the related publications of the inventors listed in the Italian Patent Application and related e-mail correspondence. A3625-A3729.

On September 3, 2013, Thermolife filed an Objection to Defendants' Supplement. A3730-A3835. On September 16, 2013, a hearing was held on the Defendant's Motion for Summary Judgment and for Attorneys' Fees under 35 U.S.C. § 285. A4147-A4187.

On October 8, 2013, the district court granted Defendants' Motion for Summary Judgment of Invalidity and held the '908 Patent invalid over the Italian Patent Application. The district court denied the Defendants' request for attorneys' fees, improperly reasoning that attorneys' fees were not warranted in part because Thermolife had retained an expert, even though the expert's opinion was based on Thermolife's flawed interpretation of the claims. A25-40; A41-A43; and A3136-A3226.

On October 17, 2013, Defendants filed a Notice of Appeal as to that portion of the Order of October 8, 2013, denying Defendants' request for attorneys' fees and the court's failure to consider the Defendants' Rule 11 Motion. A3953-A3957.

C. Statement of the Facts

1. Prosecution History

The '908 Patent claims a method, *inter alia*, of increasing testosterone levels in males by the oral ingestion of D-aspartic Acid. D-aspartic acid is a naturally occurring amino acid that is found in human beings, other mammals, amphibians, certain vegetables, and marine life (such as oysters).

The '908 Patent claims priority to a provisional application filed on March 28, 2008. The '908 Patent lists Patrick Arnold ("Mr. Arnold") as the sole inventor. A993-A996, A1865-A1881. The patent application, states, *inter alia*:

> No studies have examined the effects of D-aspartic acid or N-methyl-D-aspartate on male humans. It is well known that different species of mammals often have different responses to hormones. Therefore, it is unknown whether, and to what degree, the administration of D-aspartic acid compounds in different ways and at different levels to male humans causes an increase in levels of testosterone, growth hormone, and insulin-like growth factor 1.
>
> . . .
>
> The D-aspartic acid compound is administered in any known way that results in the compound entering the bloodstream. For example, the compound is **orally ingested**, injected directly into the

> bloodstream, administered via patches, and the like. The preferred method of administration is by oral ingestion. D-aspartic acid is well tolerated and is effectively taken into the bloodstream through the digestive tract.
>
> . . .
>
> The D-aspartic acid compound is administered in an amount that is effective to increase the levels of testosterone, growth hormone, and/or insulin-like growth factor 1 in the recipient. ***In general, the D-aspartic acid compound is administered in an amount of about 1 to 100 grams per day, preferably about 1 to 20 grams per day, and most preferably about 5 to 10 grams per day, computed on the basis of equivalent molar amount of D-aspartic acid***.
>
> [Emphasis added.]

A1377-A1537 at A1529-A1531.

On June 7, 2011, The U.S. Patent Office issued an Office Action, and rejected the pending claims over various prior art. For example, the examiner rejected the original claims 1 – 8 under 35 U.S.C. 103(a) as unpatentable over D'Aniello (Applicant cited IDS: Brain Research Reviews, 2007, 53, 215 – 234) in view of Simone (US 5,397,786). A1377-A1537 at A1496, A1498-A1504, and A1425-A1427.

On December 7, 2011, Mr. Arnold, through his counsel, filed a Response to Office Action Dated June 7, 2011, in which he argued that there was no teaching or suggestion in the cited prior art to increase testosterone levels in human males by the administration of D-aspartic acid. In particular, Mr. Arnold stated:

> D'Aniello describes the effect of intravenous administration of D-aspartic acid in rats. This results in increase in LH and testosterone in rats. However, the Examiner makes two false assumptions here: 1) That intra-peritoneal administration should have the same effect as oral administration; and 2) That if something is effective on rats it should have the same effect on humans
> . . .

A1377-A1537 at A1458-A1488.

On December 22, 2011, Mr. Arnold filed his Supplemental Response to the June 7, 2011 Office Action, in which he represented, *inter alia*:

> In addition as we previously stated, the researchers of the foregoing study themselves exclaimed at the beginning of the study in the background section that (emphasis added) [citing *The Role and Molecular mechanism of D-aspartic Acid in the Release and Synthesis of L.H. and Testosterone in Humans and Rats*, Enza Topo et al, Reproductive Biology Endocrinology, 2009; 7:120]:
>
> > "Although numerous studies have been conducted on this matter, no investigations have been until now on the effects of D-Asp on the secretion of LH and testosterone in humans, and neither has the molecular mechanism by which D-Asp triggers it action in the synthesis and release of hormones investigated"
>
> By their very own words the effects of DAA at the time of the study (almost two years after the priority date of the present patent application) on LH and testosterone secretion in HUMANS remained unknown. (Emphasis in original.)

A1377-A1537 at A1449-A1453.

On January 17, 2012, The U.S. Patent Office issued a Final Office Action rejecting all claims. The examiner rejected claims 1 – 5, 7, and 8, *inter alia*, under

35 U.S.C. § 103(a) as unpatentable over D'Aniello (Applicant cited IDS: Brain Research Reviews, 2007, 53, 215 – 234). A1377-A1537 at A1427-A1442.

On April 17, 2012, Mr. Arnold filed an Amendment After Final Rejection, wherein he amended claims 1 and 3, and cancelled claims 2, and 5 – 8. Claim 1 was amended to include the Markush group "selected from the group consisting of D-aspartic acid, D-Aspartate salts, and D-aspartate esters" purportedly to distinguish the prior art. Mr. Arnold also made the following statements to The U.S. Patent Office:

> This study/article is not prior art. Therefore, because it is peer reviewed, scrutinized, etc. this article is strong evidence that the present invention is not obvious, [citing *The Role and Molecular mechanism of D-aspartic Acid in the Release and Synthesis of L.H. and Testosterone in Humans and Rats*, Enza Topo et al, Reproductive Biology Endocrinology, 2009; 7:120] . . .
>
> Thus, by their very own words the effects of DAA at the time of the study (almost two years after the priority date of the patent application) on LH and testosterone secretion on HUMANS remained unknown. . .
>
> The examiner argues because NMDA is an analog compound of D-aspartic Acid a person of ordinary skill in the art would be motivated use [sic] for the same purposes. The examiner further argues (without evidence whatsoever placed on the record) that they are the "same compound", and that NMDA (even though not taught in Estienne) would increase levels of testosterone, growth hormone, and/or insulin-like growth factor 1 as Applicant claimed for D-Aspartic acid in Claim 8. . .

> Claim 1 has been amended. Among other things, claim 1 includes the Markush group "a D-aspartic acid, D-Aspartate salts, and D-aspartate esters" . . .
>
> Moreover the presumption of obvious based on a reference disclosing structurally similar compounds may be over come where there is a showing there is no reasonable expectation of similar properties in structurally similar compounds . . . [emphasis in the original]
>
> As evidence that there is no reasonable expectation of similar properties in DAA as compared to NMDA . . .

A1377-A1537 at A1401-A1406 and A1415.

On May 10, 2012, The U.S. Patent Office issued a Notice of Allowance. In the Notice, the examiner stated several "Reasons for Allowance," including, inter alia:

> The closest prior art are Estienne (U.S. 5,591,377), Simone (US 5,397,786) and D'Aniello (Applicant cited IDS: Brain Research Reviews, 2007, 53, 215-234) . . .
>
> The prior art D'Aniello (Brain Research Reviews, 2007) does not describe oral administration of D-Asp or do not teach administration of D-Asp to humans. The effect of D-Asp at the time of the instant application was filed on LH and testosterone secretion on humans remained unknown.

A1377-A1537 at A1387-A1392.

The two claims of the '908 Patent are:

1. A method of increasing the levels of testosterone, growth hormone, and/or insulin-like growth factor 1 in an adult male human, the method comprising administering by oral ingestion a D-aspartic acid compound selected from the group consisting of

> D-aspartic acid, D-Aspartate salts, and D-aspartate esters to an adult male human, wherein said D-aspartic acid compound is administered in an amount and for a time sufficient to increase the levels of testosterone, growth hormone, and/or insulin-like growth factor 1.
>
> 2. The method of claim 1 wherein the D-aspartic acid compound is administered in an amount of about 1 to 20 grams of D-aspartic acid equivalent.

A993-A996.

2. The Italian Patent Application

Italian Patent Application No. ITRM20050468 to Gemma D'Aniello, et al., (hereinafter "Italian Patent Application"), was filed on September 14, 2005. The Italian Patent Application was published on March 15, 2007 and issued as a patent on May 4, 2009. A1364-A1370 at A1366, ¶¶ 6 and 9; A1539-A1607; and A1620-A1659. The earliest effective filing date of the '908 Patent is March 28, 2008. The published Italian Patent Application pre-dates the '908 Patent by more than a year. Therefore, the Italian Patent Application is statutory prior art under 35 U.S.C. § 102(b). A993-A996; A1364-A1370 at A1366, ¶¶ 6 and 9; A1539-A1607; and A1620-A1659.

The Italian Patent Application describes the oral administration of D-aspartic acid (or its salts) to adult male humans in a manner that increases testosterone blood concentration levels. A particular study disclosed in the Italian Patent Application describes the oral administration of D-aspartic acid or a neutral salt

thereof (e.g., Mg, K, Na or Ca) to a group of adult males in a 90 day treatment cycle as part of an ingestion protocol. A1364-A1370 at A1366, ¶¶ 6, 9 and 12; A1539-A1607; A1620-A1659, at A1623, ¶ 6-A1624, ¶ 4; and A1672-A1766 at A1740, ¶ 1-A1741, ¶ 2.

Each adult male who was administered D-aspartic acid ingested a single 2-4 gram dose of D-aspartic acid daily. It was observed that ingestion of D-aspartic acid (or its salts) by adult males for a determined number of days induced a statistically significant increase in blood testosterone concentration:

> Furthermore, in the ambit of a study carried out on a number of volunteers, it was observed that taking **D-aspartic acid (2-4 grams, daily dose) for a defined number of days, statistically induces an increased concentration of hematic testosterone and a concomitant increase of the number and motility of spermatozoa**.

Italian Patent Application (emphasis added). A1364-A1370 at A1366, ¶¶ 6 and 9 and 12; A1539-A1607; A1620-A1659 at A1624, ¶ 2; and A1672-A1766 at A1740, ¶ 3-A1741, lns. 1-2.

In view of the foregoing, the two claims of the '908 Patent are invalid under 35 U.S.C. § 102(b) as anticipated by the Italian Patent Application.

3. The Inventor's Internet Post

On October 10, 1996, in an on-line discussion concerning the "Best Way to Legally Increase Testosterone?," Mr. Arnold disclosed "D-aspartic acid (or N-methyl-D-aspartate)." Mr. Arnold publicly posted his statement in a forum

specifically addressing "good, safe and legal methods of increasing testosterone" in human males. A1665-A1670.

At his deposition, Mr. Arnold acknowledged that the email address at issue, "parnold@net66.com," was an email address he used, and that while he had no memory of making the internet statement(s), he had no reason to deny them. A3458-A3525 at A3484-A3488.

Thermolife has agreed that it does not contest the authenticity of Mr. Arnold's internet statements. A1961-A1967 at A1961.

Mr. Arnold's internet statements were never provided to The U.S. Patent Office. A3458-A3525 at A3511.

4. The February 2008 Italian Article

In February of 2008, G. D'Aniello, E. Topo, M.A. Di Filippo, N. Grieco, T. Notari, S. Ronsini, and A. D'Aniello, published an article entitled "D-Aspartic Acid is Involved in the Release and Synthesis of LH and Testosterone" (hereinafter the "February 2008 Italian Article"). This article addressed the role of D-aspartic acid in the increase in testosterone and included a study of nine patients who ingested 2.6 grams of D-aspartic acid (Copyright 2008: University of Padova Book Publishing Cooperative). A1850-A1863.

Thus, the February 2008 Italian Article clearly establishes that the oral ingestion of D-aspartic acid over time and in amounts sufficient to increase the

level of testosterone in adult male humans was known before the application that led to the '908 Patent was filed on March 28, 2008, and hence, invalidates the '908 Patent under 35 U.S.C. § 102(a). A1850-A1863 and A1865-A1881.

Mr. Arnold testified that although he conceived his invention in 2000, he abandoned work on the invention for large periods of time over the next eight (8) years before his application was filed on March 28, 2008. A3458-A3525 at A3489-A3490; A3503-A3504; and A3509-A3510.

Mr. Arnold testified that he tested the effects of D-aspartic acid although his testing was never disclosed in his application. A1865-A1881; A3458-A3525 at A3504 and A3512-A3517.

Mr. Arnold's test records, as well as his research records, were discarded when his company became defunct in 2009. A3458-A3525 at A3505-A3508.

Thus, Mr. Arnold does not possess and cannot produce records to establish an earlier conception and reduction to practice (coupled with due diligence) before the application date of March 28, 2008. A3458-A3525 at A3505-A3508 and A3518-A3519.

5. Thermolife's Failure to Investigate and Improper Legal Arguments

On December 21, 2012, December 26, 2012 and January 25, 2013, prior to filing their respective answers and counterclaims, several of the Defendants gave written notice to Thermolife that the assertion of the '908 Patent against these

Defendants was frivolous in light of the Italian Patent Application. Thermolife was provided with a copy of the Italian Patent Application, together with a detailed explanation of why the Italian Patent Application invalidated the '908 Patent. A1672-A1766; A1771-A1776; and A1835-A1841.

On December 28, 2012, Thermolife responded, inter alia, that "[n]o evidence exists that the Italian application was present in a "printed publication" within the meaning of 102(b) or even capable of being so in 2007." A1768-A1769 and A1843-A1844.

On April 29, 2013, several of the Defendants again wrote Thermolife providing a detailed explanation of why the '908 Patent is invalid in view of the Italian Patent Application and Mr. Arnold's internet postings, including an explanation of the duty to investigate the validity of a patent being asserted. A1789-A1800.

On May 6, 2013, Thermolife responded with mere assertions, and no facts, that the Italian Patent Application was not prior art and that it did not invalidate the '908 Patent. Plaintiff also contested, without foundation, the translation of the application.[1] A44-A98 at A87 [Dkt No. 195]; A1815-A1816; and A1818-A1830 at A1822-A1826.

[1] Plaintiff subsequently withdrew its groundless dispute over the translation.

On May 22, 2013, at the Scheduling Conference before the district court, Thermolife's counsel represented that he had **not** undertaken an analysis to determine whether any claim terms needed to be construed, a critical step to determine infringement and invalidity. Thermolife initially contended that the phrase "is *administered in an amount and for a time sufficient to increase* the levels of testosterone, growth hormone, and/or insulin-like growth factor 1" as it appears in claim 1 might need to be construed, but later withdrew that contention. A1818-A1830 at A1827-A1829.

On June 13, 2013, Defendants deposed Mr. Arnold. At his deposition, he was represented by Thermolife's counsel, whom he retained at the suggestion of Ronald Kramer ("Mr. Kramer"), who is the President of Thermolife. Mr. Arnold maintains a friendship with Mr. Kramer. Mr. Arnold is a consultant to Thermolife. A1364-A1370 at A1369, ¶ 30; A1959; A3458-A3525 at A3462, A3465-A3467, A3471, A3478, A3495-A3498, and A3520-A3521.

Significantly, Mr. Arnold testified that he was **never** contacted before the commencement of this action, nor was he contacted by counsel for Thermolife after Defendants produced correspondence (and later counterclaims) concerning Mr. Arnold's internet statements and the Italian Patent Application. A3458-A3525 at A3501-A3502 and A3520. In fact, Mr. Arnold was not contacted by

Thermolife's counsel until after Defendants served Notice of his deposition on May 29, 2013.

Mr. Arnold also was never provided a copy of the Italian Patent Application (English translation), the various letters of counsel and/or Defendants' counterclaims. Counsel for Thermolife initially claimed that Mr. Arnold had no memory of his internet statements, but later agreed Thermolife would not contest their authenticity. A1961-A1967 at A1961-1963; A3458-A3525 at A3471-A3473, A3479-A3482, A3491-A3494, and A3511.

Mr. Arnold recalls signing the oath acknowledging his duty to disclose information material to patentability; however, Mr. Arnold testified that he tested the D-aspartic acid although none of his testing was disclosed in his application. A1865-A1881; A3458-A3525 at A3504, A3512-A3517, and A3522-A3523.

Mr. Arnold also testified that all of his test records, as well as his research records, were discarded when his company became defunct.[2] A3458-A3525 at A3505-A3508.

On July 15, 2013, the Defendants moved for summary judgment of invalidity based on the Italian Patent Application and other prior art and for

[2] It is significant to note that Mr. Arnold is no stranger to legal matters. Indeed, he is a convicted felon [A1951-A1957] (who defrauded the U.S. Olympic Committee and Major League Baseball in the notorious BALCO scandal involving athletes such as Marion Jones and Barry Bonds).

attorneys' fees under 35 U.S.C. § 285 on the grounds that Thermolife failed to investigate the validity of the patent, failed to consider a construction of the patent claims before the lawsuit was filed, and continued to pursue this case even though it was presented with invalidating prior art shortly after the case was filed. The Defendants also filed a Rule 11 Motion (which was stricken as premature). A44-A98 at A88-A91 and A93 [Dkt. Nos. 204, 212-215, 220 and 229].

On August 18, 2013, Thermolife filed its Opposition to Defendants' Motion for Summary Judgment. In its Opposition, Thermolife argued that the prior art must include **each member** of the Markush group to anticipate the claim, which is plainly contrary to longstanding precedent on the legal construction of Markush claims. A2912-A2936 at A2926-A2928; A2937-2974 at A2956, ¶59, A2957 at ¶62, A2961-A2962 at ¶67; and A3136-A3226 at A3139-A3143, ¶¶ 11-24.

More particularly, Thermolife asserted that the prior art must disclose: (1) the sequence "testosterone, growth hormone, **and** insulin-like growth factor 1," (2) describe **all** members of the Markush group of elements set forth in the claims; and (3) provide *ipsa verbis* description of the entire range in claim 2. Thermolife argued "Claim 2 claims about 1 to 20 grams of D-aspartic acid equivalent – not merely 2.6 grams." The Expert Declaration of Dr. Wolff was based on this flawed claim construction. A2912-A2936 at A2926-A2932; and A3136-A3151.

Mr. Moradei, an alleged expert on Italian patent law, speculated that the Italian Patent Application would be available several weeks after March 15, 2007, because of the slowness of the Italian Patent Office to produce its records on request. Mr. Moradei thus purported to contradict the legal effect of the Patent Cooperation Treaty, the Italian Industrial Property Code and the Certification of the Italian Patent Office that the Italian Patent Application was publicly available on March 15, 1997 provided by the Defendants. A1609-A1612; A1614-A1618; A1655; A1846-A1848; and A2983-A3000 at A2986-A2990, ¶¶ 12-23.

In its Opposition papers, Thermolife also submitted the Declaration of Mr. Arnold together with an uncorroborated e-mail allegedly sent to his counsel, in which he alleges that he conceived the invention on or before January 2, 2008 (to defeat the February 2008 Italian Article). Thus, the Italian Patent Application, even according to the time line offered by Mr. Moradei, i.e. that the application was available shortly after March 15, 2007, was prior art to the date of Mr. Arnold's alleged conception set forth in the e-mail of January 2, 2008, submitted with Thermolife's Opposition to Motion for Summary Judgment.[3] A2912-A2936; A2975-A2982; A2983-A3000 at A2986-A2990, ¶¶ 12-23; and A3618-A3622.

[3] In a classic case of "not seeing the forest for the trees," even if Mr. Arnold's uncorroborated testimony were correct, the Italian Patent Application would still be anticipatory prior art under 35 U.S.C. § 102(a) (versus §102(b)).

SUMMARY OF ARGUMENT

The evidence demonstrates overwhelmingly that Defendants are entitled to an award of attorney's fees under 35 U.S.C. § 285. Thermolife never interviewed the inventor prior to bringing this action even though he was a paid consultant for Thermolife and a personal friend of Thermolife's owner. The inventor destroyed all of his research and test records, making the prospect of establishing an earlier date of conception before the application date of March 28, 2008 impossible.

Further, shortly after this action began, on December 21, 2012, the Defendants provided Thermolife's counsel a copy of the Italian Patent Application, which published on March 15, 2007, and which clearly invalidated the asserted claims. Thermolife had a duty to investigate the validity of the patent when it received the prior art.

Additionally, for its claim construction, Thermolife argued that the prior art must include each member of the Markush group to anticipate the claim, which is plainly contrary to long-standing precedent on the legal construction of Markush claims. Thermolife also argued that a single data point within a claimed range did not anticipate the claimed range which was also contrary to longstanding precedent.[4]

[4] Significantly, as a matter of public record, Thermolife is well-versed in the patent litigation arena, and cannot be excused for not knowing basic construction

Attorneys' fees are appropriate where the patentee's claim construction is "contrary to all the intrinsic evidence and does not conform to the standard canons of claim construction." Thermolife's continued prosecution of this action was objectively baseless and needlessly litigious.

ARGUMENT

A. The Court Erred As A Matter Of Law By Failing to Award Defendants' Attorneys' Fees Under 35 U.S.C. § 285 and to Consider Defendants' Rule 11 Motion, As Thermolife (1) Received Prompt Notice that the '908 Patent Is Invalid; (2) Failed To Investigate the Validity of the Asserted Patent; (3) Failed to Undertake A Claim Construction Analysis Prior to Commencing the Lawsuit; and (4) Argued Several Claim Interpretations That Are Contrary To Longstanding Precedent

1. The Applicable Standard of Review

Under 35 U.S.C. § 285, a "court in exceptional cases may award reasonable attorney fees to the prevailing party." Once it is determined that the party seeking fees is a prevailing party, determining whether to award attorneys' fees under 35 U.S.C. § 285 is a two-step process. *Forest Labs., Inc. v. Abbott Labs.*, 339 F.3d 1324, 1327–28 (Fed. Cir. 2003). First, a prevailing party must establish by clear and convincing evidence that the case is "exceptional." *Id.* at 1327. An award of fees against a patentee can be made for a frivolous claim, inequitable conduct before the Patent and Trademark Office, or misconduct during litigation. *Beckman*

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principles, as it has commenced over 100 patent lawsuits throughout the United States (www.pacer.gov).

Instruments, Inc. v. LKB Produkter AB, 892 F.2d 1547, 1551 (Fed. Cir. 1989). Second, if the case is deemed exceptional, a court must determine whether an award of attorneys' fees is appropriate and, if so, the amount of the award. *Forest Labs.*, 339 F.3d at 1328. "[T]he amount of the attorney fees [awarded] depends on the extent to which the case is exceptional." *Special Devices, Inc. v. OEA, Inc.*, 269 F.3d 1340, 1344 (Fed. Cir. 2001).

As this Court noted in *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 682 F.3d 1003, 1005-06 (Fed. Cir. 2012), "the threshold objective prong ... is a question of law based on underlying mixed questions of law and fact and is subject to *de novo* review." See *also Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1236 (Fed. Cir. 2011). Additionally, as this Court very recently held in *Kilopass Technology, Inc. v. Sidense Corporation*, 2013-1193, WL6800885, at * 7 (Fed. Cir. Dec. 26, 2013), "subjective bad faith **only** requires proof that the 'lack of objective foundation for the claim 'was *either* known *or* so obvious that it should have been known' by the party asserting the claim. (emphases added) (quoting *In re Seagate Tech., LLC*, 497 F3d. 1360, 1371, (Fed. Cir. 2007) (en banc)). Thus, actual knowledge of baselessness is **not** required." (emphasis added).

2. The Prosecution of This Litigation Was Objectively Baseless

Thermolife had a duty to investigate the validity of the '908 Patent before it brought suit and when Defendants brought the Italian Patent Application to its attention on December 21, 2012. *See View Eng'g, Inc. v. Robotic Vision Sys.*, 208 F.3d 981, 986 (Fed. Cir. 2000) (affirming an award of Rule 11 sanctions against a plaintiff); *See also Thermocycle Int'l, v. A.F. Hinrichsen Sales Corp.*, 82 CIV. 5948 (TPG), 1991 WL120299, at *3 (S.D.N.Y. June 26, 1991) ("If Thermocycle's attorneys were responsible for commencing a patent infringement action when they knew that their client's patent was invalid, or when they had no reasonable ground to believe in the patent's validity, this would clearly justify the imposition of sanctions under Rule 11.").

Thermolife made no effort to contact the inventor, either before it commenced this litigation or after it received a copy of the Italian Patent Application and the inventor's prior internet post, even though the inventor was a personal friend of the owner of Thermolife and a paid consultant. Thermolife's counsel later represented the inventor at his deposition. At his deposition, it was quickly established that the test records and research materials relating to the invention had been destroyed during the prosecution of the patent.

The destruction of documents meant that the inventor would not be able to prove an earlier date of invention, coupled with due diligence and reduction to practice, before the patent application date of March 28, 2008.

Later, in its Opposition papers, Thermolife submitted a Declaration of the inventor together with an uncorroborated e-mail to his counsel, for the purpose of attempting to argue that he had conceived of his invention on or before January 2, 2008, in an attempt to "swear behind" the February 2008 Italian Article. This factual assertion, even if taken as true, would not remove the Italian Patent Application as a prior art reference under 35 U.S.C. § 102(a). According to Mr. Moradei's opinion, even taking into account how poorly he claims the Italian Patent Office operated in March of 2007, the Italian Patent Application would have been available some thirty days or so from the March 15, 2007 publication date (by operation of Article 53 of the Italian Industrial Property Code).

Thus, an investigation would have revealed that the Italian Patent Application was prior art under 35 U.S.C. §102(a). Plaintiff had a duty to withdraw its claims of infringement after being advised of prevailing facts that removed the basis for its claims. *See Phonometrics, Inc. v. Econ. Inns of Am.*, 349 F.3d 1356 (Fed. Cir. 2003) (Rule 11 sanctions affirmed by Federal Circuit where plaintiff refused to withdraw infringement claims, and continued to submit briefs in support thereof, in the face of a change in law and a Rule 11 safe-harbor letter).

Knowingly asserting an invalid patent warrants an award of fees under 35 U.S.C. Section 285 of the Patent Act for "engaging in vexatious or unjustified litigation." *Eon-Net LP v. Flagstar Bancorp,* 653 F.3d 1314, 1324 (Fed. Cir. 2011) (an award of fees under Section 285 is appropriate if "(1) the patentee brought the litigation in bad faith; and (2) the litigation is objectively baseless.").

This statute applies equally to Thermolife. "[T]here is and should be no difference in the standards applicable to patentees and infringers who engage in bad faith litigation. The different interests of the patentee and alleged infringer are adequately taken into account in the required evaluation of the totality of the circumstances." *Eltech Sys. Corp. v. PPG Indus., Inc.*, 903 F.2d 805, 811 (Fed. Cir. 1990); *see also Ericsson, Inc. v. Harris Corp.*, CIV. A. 3-98-CV-2903 M, 2001 WL 257838, at *5 (N. D. Tex. March 12, 2001) ("there is no difference in the standards applicable to patentees and accused infringers accused of engaging in bad faith litigation.") (*citing Eltech*, 903 F.2d at 811).

The district court committed clear error when it failed to hold that Thermolife's failure to investigate the validity of the patent and continued prosecution of this case was undertaken objectively in bad faith. The court further erred when it failed to award fees under 35 U.S.C. § 285 and consider the Defendants' Rule 11 Motion.

3. Thermolife's Proposed Claim Construction and Accompanying Expert Declaration Ignored Nearly A Century of Precedent and Independently Establish That Attorney's Fees Are Warranted

As disclosed by Thermolife at the Scheduling Conference, Thermolife did not undertake a construction of the asserted patent claims prior to commencing this action, a necessary step to determine infringement. In its Summary Judgment Opposition papers, its claim construction position was frivolous. Thermolife argued that the prior art must disclose: (1) the sequence "testosterone, growth hormone, **and** insulin-like growth factor 1;" (2) describe **all** members of the Markush group of elements set forth in the claims; and (3) provide *ipsa verbis* description of the range in claim 2.

The sequence "testosterone, growth hormone, and/or insulin-like growth factor 1" appears twice in the claim, i.e. in the claim preamble and the claim body. The U.S. Patent Office has consistently construed the term "and/or" to have the ordinary and customary meaning of "to indicate that two words or expressions are to be taken together or individually." *See*, e.g., Ex parte Gomoll, 2013 WL 4028118, at *3 (Patent Tr. & App. Bd., August 5, 2013), (citing http://www.merriam-webster.com/dictionary/and/or (last visited: July 19, 2013). It is also well known that the phrase "and/or" is conjunctive and is used, by definition, as:

> a function word to indicate that two words or expressions are to be taken **together or individually** [emphasis added].

"And/or." Merriam-Webster.com. Merriam-Webster, n.d. Web. 9 Aug. 2013. <http://www.merriam-webster.com/dictionary/and/or>.

The interpretation of the term "or" compels the same conclusion. In *Schumer v. Lab. Computer Sys., Inc*., 308 F.3d 1304, 1311 (Fed. Cir. 2002), for the construction of the word "or," the court held "the proper approach is to construe the claim language using standard dictionary definitions, because here, the claims have no specialized meaning."[5] The court stated it has "consistently interpreted the word "or" to mean that the items in the sequence are alternatives to each other." *Id.* Thus, the court held that if one member of the sequence is found in the accused method, infringement occurs. *Id.* at 1312. Notably, it has been consistently held "[t]hat which infringes, if later, would anticipate, if earlier." *Peters v. Active Mfg. Co*., 129 U.S. 530, 537 (1889); s*ee also Upsher-Smith Labs., Inc. v. Pamlab*, L.L.C., 412 F.3d 1319, 1322 (Fed. Cir. 2005).

Words of a claim are generally given their ordinary and customary meaning. *Phillips v. AWH Corp*., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (citing *Vitronics Corp. v. Conceptronic, Inc*., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). There is nothing in the specification of the '908 Patent to indicate any special meaning

[5] Thermolife cited *Schumer* in its Opposition papers but ignored its holding. A2919.

given to the phrase "and/or." Rather, the phrase "and/or" signals that the sequence "testosterone, growth hormone, and/or insulin-like growth factor 1" is an individual or collective alternative to one another. Thus, if one member of this sequence is found in the prior art, the sequence is anticipated. *Peters v. Active Mfg. Co.*, 129 US at 537.

Thermolife's arguments and expert testimony that prior art must include all elements of the sequence "the levels of testosterone, growth hormone, and/or insulin-like growth factor 1" as opposed to any one of the listed elements is baseless and contradicts the ordinary meaning accorded the language of the claim. On this basis, Defendants objected to Thermolife's expert testimony.

A similar analysis applies to the Markush language in the claims, i.e., "a D-aspartic acid compound selected from the group consisting of D-aspartic acid, D-aspartate salts, and D-aspartate esters." This claim element "is written in Markush form. Ex. parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925). A Markush form recites 'alternatives." Manual of Patent Examination Procedure, §§ 803.2 and 2173.05(h) (8th ed. 2012), Markush Claims. Thus, the entire element is disclosed by the prior art if one alternative in the Markush group is in the prior art. *Fresenius USA, Inc. v. Baxter Int'l, Inc*., 582 F.3d 1288, 1298 (Fed. Cir. 2009).

Thermolife's arguments in the district court ignored nearly ninety years of judicial precedent concerning the construction of a Markush group. This Court has

previously reversed and remanded the denial of attorneys' fees and Rule 11 sanctions where the patentee's claim construction was "contrary to all the intrinsic evidence and does not conform to the standard canons of claim construction." *Raylon, LLC v. Compuls Data Innovations, Inc*., 700 F.3d 1361, 1369 (Fed. Cir. 2012):

> Applying the objectively reasonable standard, we agree with defendants that Raylon's claim construction (and thus infringement contentions) were frivolous. Claim construction is a matter of law, so that an attorney's proposed claim construction is subject to Rule 11(b)(2)'s requirement that all legal arguments be nonfrivolous. *Antonious v. Spalding & Evenflo Cos., Inc*., 275 F.3d 1066, 1071 (Fed. Cir. 2002). Reasonable minds can differ as to claim construction positions and losing constructions can nevertheless be nonfrivolous. But, there is a threshold below which a claim construction is "so unreasonable that no reasonable litigant could believe it would succeed," *iLOR, LLC v. Google, Inc.*, 631 F.3d 1372, 1378 (Fed. Cir. 2011), and thus warrants Rule 11 sanctions.

see also Taurus IP, LLC, v. DaimlerChrysler Corp., 726 F.3d 1306, 1327 (Fed. Cir. 2013) (citing *Raylon*) ("no reasonable litigant in Taurus's position could have expected a finding that a web surfer acceding the accused external website satisfied the requirement for a 'user,' as recited in claims 16. Although reasonable minds can differ on claim construction positions, Taurus's proposed construction of 'user,' and the related terms discussed above, fall below the threshold required to avoid a finding of objective baselessness.").

Thermolife's claim construction was thus baseless. Thermolife should not be permitted to escape the application of 35 U.S.C § 285 merely because its expert adopted its frivolous claim construction.

For the forgoing reasons, the district court committed error when it failed to determine this case was objectively baseless and award attorneys' fees under 35 U.S.C. § 285, and failed to consider the Defendants' Rule 11 Motion.

CONCLUSION AND STATEMENT OF RELIEF SOUGHT

Defendants are entitled to an award of attorney's fees under 35 U.S.C. § 285. Thermolife never interviewed the inventor prior to bringing this action. The inventor destroyed all of his research and test records, making the prospect of establishing an earlier date of conception before than the application filing date of March 28, 2008 impossible.

Shortly after this action began, on December 21, 2012, Defendants provided Thermolife's counsel a copy of the Italian Patent Application, which published on March 15, 2007, and which clearly invalidated the asserted claims of the '908 Patent. Thermolife failed to investigate the validity of the patent when it received the prior art.

For its claim construction, Thermolife argued that the prior art must include each member of the Markush group to anticipate the claim, which is plainly contrary to long-standing precedent on the legal construction of Markush claims.

Thermolife also argued that a single data point within a claimed range did not anticipate the claimed range which also is contrary to longstanding precedent.

Attorneys' fees are appropriate. The case should be remanded to the District Court for the Central District of California for an award of attorneys' fees under 35 U.S.C. § 285 and for consideration of the Defendants' Rule 11 Motion.

Respectfully submitted,

Dated: January 13, 2014

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Dated: January 13, 2014

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ADDENDUM

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	CV 12-09229 GAF (FFMx)	Date	October 8, 2013
Title	ThermoLife International LLC v. Better Body Sports LLC et al		

Present: The Honorable	**GARY ALLEN FEESS**	
Stephen Montes Kerr	None	N/A
Deputy Clerk	Court Reporter / Recorder	Tape No.
Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:	
None	None	

Proceedings: **(In Chambers)**

ORDER RE: DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

I.
INTRODUCTION

Plaintiff Thermolife International, LLC ("Thermolife" or "Plaintiff") owns United States Patent No. 8,202,908 ("the '908 Patent"), titled "D-Aspartic Acid Supplement." (Docket No. 1 [Complaint ("Compl.")] ¶ 2.) The '908 Patent describes a method for increasing testosterone levels in human males through the ingestion of D-Aspartic Acid compounds. Thermolife has filed multiple lawsuits in this district in which it contends that the numerous named defendants have infringed on the patent by manufacturing, advertising, distributing or selling dietary supplements that contain D-Aspartic Acid compounds that are indistinguishable from those covered by the '908 patent.[1]

Defendants do not dispute that their products contain D-aspartic acid and are designed to increase male testosterone levels. Defendants, however, contend that the Court need not reach the question of infringement because the patent is invalid. Accordingly, they now jointly move for summary judgment of invalidity. (Docket No. 212 [Motion for Summary Judgment ("Mem.")] at 10.) They argue that the patent's claims were fully anticipated in the prior art

[1] The complaints name the following defendants: Bio-Engineered Supplements and Nutrition Inc; Bronson Laboratories Inc; Hi-Tech Pharmaceuticals Inc; Infinite Labs LLC; Lecheek LLC; Maximum Human Performance LLC; Muscle Warfare Inc; Nutrex Research Inc; Pharmafreak Holdings Inc; Purus Labs Inc; Reaction Nutrition LLC; SNI LLC; Lone Star Distribution; All Star Health; Redefine Nutrition LLC; S A N Nutrition Group; GNC Corporation; General Nutrition Centers Inc; General Nutrition Corporation; Kilosports Inc; DNA Sports Nutrition; Nutrition Zone Worldwide Inc; and Nutraplanet.

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before the purported inventor, Patrick Arnold, applied on March 28, 2008, for what became the '908 Patent. Defendants cite in support of their invalidity claim a March 15, 2007, Italian patent application titled "Use of D-Aspartic Acid of Its Salts for the Treatment of Male Infertility" (the "Italian Patent Application"). They also submit evidence regarding a 1996 internet post by Arnold who advised a questioner in an internet chat room that D-Aspartic Acid is a legal means of increasing testosterone levels and a February 2008 journal article addressing the use of D-Aspartic Acid in the release and synthesis of LH and testosterone. Defendants also argue that, because the infringement suit is so frivolous that it qualifies as an "exceptional case" under 35 U.S.C. § 285, they are entitled to their attorney's fees. Thermolife does not dispute the facts on which Defendants rely but opposes these motions principally on the grounds that the items do not qualify as prior art as that term is used in patent jurisprudence and that, even if they did, these items do not disclose the subject matter of the'908 Patent. Thermolife therefore contends that the invalidity challenge fails and, plainly, that the motion for attorney's fees must also be denied.

Having considered the undisputed facts presented in this motion, the Court concludes that they support Defendants' motion. The 2007 Italian Patent Application constitutes prior art that discloses the subject matter of the '908 Patent. That single prior art reference is sufficient to invalidate the '908 Patent. The motion for summary judgment is **GRANTED**. However, the Court is not persuaded that the lawsuit can be characterized as "frivolous" under controlling precedent and **DENIES** the motion for attorney's fees. The Court explains its reasoning in detail below and begins with a discussion of the undisputed material facts.

II.
FACTS

A. THE ITALIAN PATENT APPLICATION

In 2005, three Italian inventors filed an application for a patent bearing the title "Use of D-Asparatic Acid or its Salts for the Treatment of Male Infertility." (Docket No. 214-11, Ex. 5.) The application was published on March 15, 2007. The application contains a discussion of work performed by the authors establishing that "D-aspartic acid . . . is involved in male fertility." (Ex. 5, at 257.) The application then describes, in great detail, increases in sperm count obtained through the use of the compound. Following a discussion of relevant numerical data, the application states:

> [I]n the context of a study conducted on volunteers, it was observed that ingestion of D-aspartic acid (2-4 gram daily dose) for a determined

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> number of days induces a statistically [significant] increase ***in blood testosterone concentration*** and a concomitant increase in sperm count and sperm motility.

(Id. at 258.) (Emphasis added.) Notably, the Italian Patent Application offers a description of the compound as consisting of not only D-aspartic acid, but orange flavoring, vanillin, fructose, maltodextrin, aspartame, and pure dehydrated orange juice, among other ingredients. (Id. at 263–64.) These flavoring additives imply that the compound is to be ingested orally.

In the interest of building a thorough record, the Court requested that Defendants provide a copy of the underlying study referenced in the Italian Patent Application. (Docket No. 233 [8/22/13 Order].) Defendants filed a copy of what they purported was the unpublished study referenced in the Italian Patent Application on August 30, 2013. (Docket No. 238 [Supplement to Motion for Summary Judgment].) However, Thermolife then proceeded to file an Objection to the study, explaining that because "the document submitted by Defendants contains references to events in 2006 and 2007," and the Italian Patent Application was filed in September 2005, "the 'study' submitted by Defendants **is not** and **cannot be** the unpublished 2005 Italian study requested by the Court . . . ." (Docket No. 240 [Objection] at 1.) Defendants were ultimately unable to locate any earlier version or copy of the underlying study.

However, Defendants argued persuasively—both in their briefing and at the hearing on this matter—that "[t]he sole question before this Court is whether the asserted claims of the '908 patent are anticipated by the 2005 Italian Patent Application." (Docket No. 244 [Defendants' Response to Objection ("D Resp.")] at 3.) "[I]nvalidity by anticipation requires that the four corners of a single[] prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282 (Fed. Cir. 2000). And, as discussed in detail below, the Court concludes that the four corners of the Italian Patent Application describes every element of the '908 Patent, and that review of the underlying study is therefore unnecessary to the resolution of this motion. The Court therefore declines to devote any further analysis to the issue of the authenticity of the underlying study Defendants submitted to the Court.

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B. OTHER PRIOR ART REFERENCES

The Italian Patent Application is sufficient—on its own—to invalidate the '908 Patent. However, in order to provide necessary context, the Court offers a brief synopsis of the other potentially invalidating prior art references identified by Defendants.

1. THE FEBRUARY 2008 ITALIAN ARTICLE, ENTITLED "D-ASPARTIC ACID IS INVOLVED IN THE RELEASE AND SYNTHESIS OF LH AND TESTOSTERONE"

In February 2008, G. D'Aniello, E. Topo, M.A. Di Filippo, N. Grieco, T. Notari, S. Ronsini, and A. D'Aniello published an article entitled "D-Aspartic Acid is Involved in the Release and Synthesis of LH and Testosterone." (Mem. at 14.) The article addressed the role of D-aspartic acid in the increase in testosterone and included a study of nine patients who ingested 2.6 grams of D'aspartic acid. (Id.) The article states, in relevant part:

> . . . We thus conducted a study on a group of nine healthy volunteers ranging in age from 27 to 67 years. The following protocol was followed: before treatment with D-Asp was begun, we measured serum testosterone and LH between 10:00 and 10:30 in the morning, with an eye toward minimizing the fluctuations of LH and testosterone in the plasma [11]. Patients were asked to ingest, for 10 days, a dose of sodium D-aspartate (2.6 g of sodium D-aspartate) commercialized in Italy under the name DADAVIT (Pharmaguida S.r.l. Italy). The supplement [sic; test drug] was ingested [after being] dissolved in water and administered in the morning after breakfast. When the treatment cycle was completed, the concentrations of LH and testosterone were determined in all patients on the 1st, 11th, and 21st days after the ingestion ended. The obtained results, although [based] on only 9 patients at this time, indicate that sodium D-aspartate is responsible for increasing LH and testosterone plasma levels in man and that this increase is statistically significant. In fact, as reported in Table 1, the serum concentration of LH measured the day after the ingestion cycle was completed (1st day) showed an increment between 18[%] and 112%, with a mean of 40.7% over baseline values (Table 1: values of column 2 versus those of column 1). This difference was statistically significant, with a P value <0.002. On the 11th day after suspension of the treatment, 4 of the 9 patients still showed increases of plasma LH over baseline values. However, this increment was not statistically significant (Table 1, value[s] of column 3 versus those of column 1). On the 21st day

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> after the end of the therapy, the LH concentrations returned to baseline levels in all patients (Table 1) . . . ."

(Mem. at 15 (citing [Statement of Undisputed Facts ("SFL")] ¶ 79).) The Court agrees that "the Italian article clearly establishes that the oral digestion of D-aspartic acid over time and in amounts sufficient to increase the level of testosterone in adult male humans was known before the application that led to the '908 patent was filed on March 28, 2008." (Id.) However, Thermolife insists that Patrick Arnold, the inventor of the'908 Patent, conceived of his idea prior to the publication of the February 2008 Article. Thermolife has submitted an email from Arnold to his former patent attorney, Philip Bateman, in support of this contention. (Docket No. 226, Ex. A.)

2. ARNOLD'S INTERNET POSTINGS

On October 10, 1996, in an online discussion forum titled "Best Way to Legally Increase Testosterone," Arnold publicly posted that D-aspartic acid could be used to increase testosterone. The forum exchange reads as follows:

> Nobody<nowh...@noplace.com>writes:
> >cole wrote:
> >>What are some good, safe and legal methods of increasing testosterone
> >>levels? I know that working out hard will obviously do this,
> but
> >>what are some other methods/foods/supplements that will help? Thanks.
> >>Billy . . .
> ....
> Patrick Arnold View profile Hide options Oct 10 1996, 3:00
> am
> Newsgroups: misc.fitness.weights
> From:parn...@net66.com (Patrick Arnold)
> Date: 1996/10/10
> Subject: Re: Best way to legally increase testosterone?
> Print Individual Message Show original Report this message
> Find messages
> by this author
> 1)androstenedione
> 2) D-aspartic acid (or N-methyl-D-Aspartate)
> PA

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(Mem. at 13–14 (citing SFL ¶ 63).) At his deposition, Arnold acknowledged that he used the email address at issue—parnold@net66.com—and that while he had no memory of making these statements, he had no reason to deny them. (Id. (citing SFL ¶¶ 92–93).)

3. ABSTRACT 401, ARTICLE ENTITLED "DO MARINE MOLLUSKS POSSESS APHRODISIACAL PROPERTIES?"

Defendants offer only the following information—in a footnote—about this piece of allegedly invalidating prior art: "The '908 Patent is also anticipated or at a minimum rendered obvious by an oyster study that discloses the use of D-Aspartic acid to increase male testosterone." (Mem. at 15 n.5 (citing Abstract 401 of the American Chemical Society National Meeting, presented on March 13–17, 2005 (SFL ¶¶ 64, 65)).) Defendants elaborate no further on the contents of this study.

C. THE '908 PATENT

1. HISTORY OF PROSECUTION

On March 28, 2008, Arnold submitted a provisional patent application to the United States Patent and Trademark Office ("USPTO") for a D-aspartic acid supplement. The application was assigned application number 61/072,254. A utility patent application, no. 12/383,682, which claimed priority to the provisional application, was filed on March 27, 2009, and issued June 19, 2012, as the '908 Patent. Arnold is listed as the sole inventor. (SFL ¶¶ 1–4.) In the utility patent application, Arnold made the following representations to the USPTO:

> No studies have examined the effects of D-aspartic acid or N-methyl-D-aspartate on male humans. It is well known that different species of mammals often have different responses to hormones. Therefore, it is unknown whether, and to what degree, the administration of D-aspartic acid compounds in different ways and at different levels to male humans causes an increase in levels of testosterone, growth hormone, and insulin-like growth factor 1.
>
> Accordingly, there is a demand for a method of improving the physical condition of adult male humans of all ages by increasing their levels of testosterone, growth hormone, and all insulin-like growth factor 1 without the administration of hormones or prohomones.

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> . . .
>
> I have invented a method of improving the physical condition of an adult male human. The method comprises administering an effective amount of a D-aspartic acid compound to an adult male human.
>
> The method of this invention improves the physical condition of adult male humans of all ages by increasing their levels of testosterone, growth hormone, and/or insulin-like growth factor 1 without the administration of hormones. The method comprises the administration of D-aspartic acid and/or its biological equivalent derivate compounds. D-aspartic acid is a chemical that is present in the human body and is generally recognized as safe.

(Mem. at 5 (citing SFL ¶¶ 5–13).) However, Arnold's initial patent application was rejected on June 7, 2011, in light of several prior art references, including D'Aniello (Applicant cited IDS: Brain Research Reviews, 2007, 53, 215–234). (SFL ¶¶ 22–26.) On December 7, 2011, Arnold filed a response to the June 7 Office Action, in which he expanded on his representation that there was no teaching or suggestion in the cited prior art that the administration of D-aspartic acid could be used to increase testosterone levels in human males. Specifically, Arnold explained:

> D'Aniello describes the effect of intravenous administration of D-aspartic acid in rats. This results in increase in LH and testosterone in rats. However, the Examiner makes two false assumptions here: 1) That intra-peritoneal administration should have the same effect as oral administration; and 2) That if something is effective on rats it should have the same effect on humans.
>
> . . .
>
> The applicant, prior to applying for the patent, conducted research to prove D-aspartic acid does indeed increase testosterone levels in humans and established a dosing regime. This by itself is true research and the patent office should endorse it as it promotes invention . . . .

(SFL ¶¶ 27–33.) Arnold filed a Supplemental Response in December 22, 2011. (Id. ¶¶ 34–38.) Notwithstanding these additional filings, the USPTO issued a final rejection in an Office Action mailed on January 17, 2012. (Id. ¶¶ 41, 42.)

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Arnold then filed an Amendment After Final Rejection on April 17, 2012. His initial application had contained eight claims; Arnold's April 17 Amendment cancelled claims 2 and 5-8, and amended claims 1 and 3. In particular, Claim 1 was amended to include the Markush group "selected from the group consisting of D-aspartic acid, D-aspartate salts, and D-aspartate esters."[2] Finally, on May 10, 2012, the Patent Office issued a Notice of Allowance. In the Notice, the examiner enumerated several "Reasons for Allowance," including:

> The prior art D'Aniello (Brain Research Reviews, 2007) does not describe oral administration of D-Asp or do [sic] not teach administration of D-Asp to humans. The effect of D-Asp at the time of the instant application was filed on LH and testoterone secretion on humans remained unknown.

(Mem. at 10 (citing SFL ¶¶ 50–52).)

2. PATENT AWARD - THE '908 PATENT AND PERTINENT CLAIMS

Following the Notice of Allowance, the USPTO awarded Arnold United States Patent No. 8,202,908, titled "D-Aspartic Acid Supplement." The '908 Patent consists of two claims and describes a method of increasing testosterone levels in males:

> 1. A method increasing the levels of testosterone, growth hormone, and/or insulin-like growth factor 1 in an adult male human, the method comprising administering by oral ingestion a D-aspartic acid compound selected from the group consisting of D-aspartic acid, D-Aspartate salts, and D-aspartate esters to an adult male human, wherein said D-aspartic acid compound is administered in an amount and for a time sufficient to increase the levels of testosterone, growth hormone, and/or insulin-like growth factor 1.
>
> 2. The method of claim 1 wherein the D-aspartic acid compound is administered in an amount of about 1 to 20 grams of D-aspartic acid equivalent.

[2] Claim 1 originally read, "A method of improving the physical condition of an adult male human, the method comprising administering an effective amount of a D-aspartic acid compound to an adult male human." (Mem. at 6 (citing SFL ¶¶ 14–21).)

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(SFL ¶ 53.) The patent was issued on June 19, 2012, and Thermolife, which is now "the owner and assignee of [the '908 Patent]," (Compl. ¶ 2.), quickly filed a series of lawsuits claiming patent infringement.

3. LAWSUIT

This action was filed on October 26, 2012. (Compl.) On December 21, 2012, several of the Defendants—Lecheek LLC, Maximum Human Performance, Purus Labs, Inc., Reaction Nutrition LLC, Redefine Nutrition LLC, John's Lone Star Distribution, Inc., and All Star Health—gave written notice to Plaintiff that the assertion of the '908 Patent against these Defendants was frivolous in light of the Italian Patent Application. (Id. ¶ 66.) In December 2012 and January 2013, Defendants Bio-Engineered Supplements and Nutrition, Inc., Bronson Laboratories, PharmaFreak Holdings, Inc., and Muscle Warfare sent Plaintiff similar notices regarding the Italian Patent Application. (Id. ¶¶ 67–69.)

Plaintiff, however, continues to maintain that the Italian Patent Application does not qualify as prior art and that it therefore does not invalidate the '908 Patent.

4. DESTRUCTION OF DATA

Despite having filed suit and undoubtedly being aware of the significance of the data purportedly supporting his application, the inventor, Patrick Arnold, has been unable to produce the results of testing he allegedly conducted that support the assertions in his patent application. At his June 13, 2013, deposition, Arnold testified that he recalled signing the oath acknowledging his duty to disclose information material to patentability to the USPTO. He also testified that he tested D-aspartic acid, despite the fact that none of his testing data was disclosed in his application. (SFL ¶¶ 2, 98, 105.) Significantly, Arnold testified that his test records and research records were all discarded or destroyed when his company became defunct, and that he therefore could no longer access or provide copies of the data. (Id. ¶¶ 100, 101.)

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III.
DISCUSSION

A. SUMMARY JUDGMENT STANDARD

Summary judgment is proper where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(a). Thus, when addressing a motion for summary judgment, the Court must decide whether there exist "any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986).

The moving party has the burden of demonstrating the absence of a genuine issue of fact for trial, which it can meet by presenting evidence establishing the absence of a genuine issue or by "pointing out to the district court . . . that there is an absence of evidence" supporting a fact for which the non-moving party bears the burden of proof. Celotex Corp. v. Catrett, 477 U.S. 317, 325 (1986). To defeat summary judgment, the non-moving party must put forth "affirmative evidence" that shows "that there is a genuine issue for trial." Anderson, 477 U.S. at 256–57. This evidence must be admissible. See Fed. R. Civ. P. 56(c), (e). The non-moving party cannot prevail by "simply show[ing] that there is some metaphysical doubt as to the material facts." Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). Rather, the non-moving party must show that evidence in the record could lead a rational trier of fact to find in its favor. Id. at 587. In reviewing the record, the Court must believe the non-moving party's evidence, and must draw all justifiable inferences in its favor. Anderson, 477 U.S. at 255.

B. APPLICATION

1. INVALIDITY

a. Threshold Issue – Claim Construction

Generally, in order to analyze a patent's validity or to determine whether a particular patent has been infringed, the claims of the patent must first be construed to determine their proper scope and content. See, e.g., Nazomi Communications, Inc. v. Arm Holdings, PLC, 403 F.3d 1364, 1367–68 (Fed. Cir. 2005) (citing Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998)). Claim construction, including terms of art, is a question of law

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exclusively within the province of the Court. Markman v. Westview Instruments, Inc., 517 U.S. 370, 387 (1996). However, Defendants contend—and the Court agrees—that it is unnecessary to conduct a full-fledged Markman hearing in order to rule on their invalidity argument. Instead, the Court need only briefly address Plaintiff's contention that the Italian Patent Application "does not disclose each claim limitation described in the '908 Patent." (Docket No. 226 [Opposition ("Opp.")] at 11.)

Specifically, Plaintiff insists that the Italian Patent Application (1) fails to disclose the sequence "testosterone, growth hormone, and insulin-like growth-factor 1," (2) fails to disclose "that D-aspartic acid itself, D-Aspartate salts (except those neutral salts specifically listed) or D-aspartate ester compounds were ingested,'"(Wolff Decl. ¶ 18), and (3) fails to disclose the "1–20 grams" range of D-aspartic acid in claim 2 of the '908 Patent. (Opp. at 11–12.) But established claim construction principles make clear that these distinctions are meaningless.

First, with respect to Thermolife's contention that the Italian Patent Application fails to disclose the sequence "testosterone, growth hormone, and insulin-growth factor 1," the Court notes that Thermolife has misquoted the language of the '908 Patent. The language actually reads "testosterone, growth hormone, and/or insulin-like growth factor 1." (See '908 Patent, Claim 1.) The USPTO has consistently construed the term "and/or" to have the ordinary and customary meaning of "to indicate that two words or expressions are to be taken together or individually." See, e.g., Ex parte Gomoll, 2013 WL 4028118, at *3 (Patent Tr. & App. Bd., August 5, 2013). "Thus, if one member of this sequence is found in the [Italian Patent Application], the sequence is anticipated." (Docket No. 231 [Reply] at 5.) And here, the Italian Patent Application clearly discloses increases in testosterone.

Thermolife's argument that the Italian Patent Application fails to disclose "that D-aspartic acid itself, D-Aspartate salts (except those neutral salts specifically listed) or D-aspartate ester compounds were ingested" falls prey to a similar challenge. The relevant language in claim 1—"a D-aspartic acid compound selected from the group consisting of D-aspartic acid, D-aspartate salts, and D-aspartate esters"—is written in Markush form. Ex parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925). A Markush form recites "alternatives." See Manual of Patent Examination Procedure, §§ 803.2 and 2173.05(h) (8th ed. 2012), Markush Claims. Thus, the entire element is disclosed by the prior art if one alternative in the Markush group is in the prior art. See Fresenius USA, Inc. v. Baxter International, Inc., 582 F.3d 1288, 1298 (Fed. Cir. 2009). The Italian Patent Application unambiguously discloses use of D-aspartic acid and thus contains one of the alternatives listed in the Markush group.

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Finally, Thermolife's argument regarding the divergent dosages disclosed in the '908 Patent and the Italian Patent Application are unavailing because "[i]t is . . . an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is 'anticipated' if one of them is in the prior art." Titanium Metals Corp. v. Banner, 778 F.2d 775 (Fed. Cir. 1985). "Thus, Plaintiff's argument and expert testimony that the [Italian Patent Application disclosing] 2–4 grams of D-aspartic acid equivalent does not anticipate [the 1–20 gram range in the '908 Patent], is plainly wrong, as a matter of law." (Reply at 6.)

The Court therefore concludes that, as a matter of claim construction, the Italian Patent Application discloses the subject matter of the '908 Patent. The Court now turns to Defendants' argument that the '908 Patent is invalid as anticipated under 35 U.S.C. § 102.

b. Anticipation: Governing Statute and Controlling Case Law

A patent claim is invalid as anticipated under 35 U.S.C. § 102 if a single prior art reference contains, either explicitly or implicitly, all of the elements of the claim." B-K Lighting, Inc. v. Vision3 Lighting, No. CV 06–02825, 2013 WL 941839, at *11. (citing Oakley, Inc. v. Sunglass Hut International, 316 F.3d 1331, 1339 (Fed. Cir. 2003) ("A determination that a claim is invalid as being anticipated or lacking novelty under 35 U.S.C. § 102 requires a finding that 'each and every limitation is found either expressly or inherently in a single prior art reference."). And "[a]lthough anticipation is a question of fact, where there are no 'genuine factual disputes underlying the anticipation inquiry, the issue is ripe for judgment as a matter of law." Id. (citing SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1343 (Fed. Cir. 2005), cert. denied, 547 U.S. 1218 (2006)). Evidence of anticipation, like all questions of invalidity, "must be clear as well as convincing." Schumer v. Lab. Computer Sys., Inc., 308 F.3d 1304, 1315 (Fed. Cir. 2002); see Semiconductor Energy Lab. Co. Ltd. v. Chi Mei Optoelectronics Corp., 531 F. Supp. 2d 1084, 1105 (N.D. Cal. 2007) ("The burden of proof in all instances falls upon the party seeking to establish the invalidity of a patent claim, who 'must overcome the presumption of validity in 35 U.S.C. § 282 by clear and convincing evidence.'" (citation omitted)).

"Anticipation is typically established by one skilled in the art who must 'identify each claim element, state the witness['] interpretation of the claim element, and explain in detail how each claim element is disclosed in the prior art reference.'" Lucent Technologies, Inc. v. Microsoft Corp., 544 F. Supp. 2d 1080, 1091 (S.D. Cal. 2008) (quoting Schumer, 308 F.3d at 1315). This testimony must be clear, as it is not "the task of the district court to attempt to interpret confusing or general testimony to determine whether a case of invalidity has been made

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out, particularly at the summary judgment stage." Id. at 1316. However, such expert testimony is not a necessary prerequisite to a determination of invalidity because in many cases, "the technology will be 'easily understandable without the need for expert explanatory testimony.'" Advanced Technology Materials, Inc. v. Praxair, Inc., 228 Fed. App'x 983, 985 (Fed. Cir. 2007) (citation omitted).

c. Thermolife's '908 Patent is Anticipated By The Italian Patent Application and Thus Invalid

Here, Defendants urge that "both claims 1 and 2 [of the '908 Patent] are anticipated by [] Italian Patent Application" No. ITRM20050468 issued to Gemma D'Aniello, et al. (Mem. at 10, 21 (citing SFL ¶¶ 53–62).) As an initial matter, the Italian Patent Application qualifies as prior art under 35 U.S.C. § 102(b) because the Italian Patent Application predates the provisional application for the '908 Patent by more than a year. The Italian Patent Application "was filed on September 14, 2005" and was ultimately "published on March 15, 2007." (Id. at 10 (citing SFL ¶ 54).) And both parties agree that "[t]he earliest effective filing date of the '908 Patent is March 28, 2008." (Id. at 11; Opp. at 6.)

Thermolife offers two arguments in opposition: (1) that "[t]he Italian Application is not a printed publication" and (2) that "[t]he Italian Application does not disclose the subject matter of the '908 Patent." (Opp. at 6, 10.) Neither argument is persuasive.

i. The Italian Patent Application Qualifies As a Printed Publication

"[T]o qualify as a printed publication, the [] publication must have been disseminated or otherwise made accessible to persons interested and ordinarily skilled in the subject matter to which the [publication] relates prior to the critical date." Orion IP, LLC v. Hyundai Motor Am., 605 F.3d 967, 974 (Fed. Cir. 2010). Thermolife explains that, although the Italian Patent Application "was initially filed on September 14, 2005, . . . [u]nder Italian law, the earliest that the Italian Application could have been made available by special request to the public was eighteen months later—March 15, 2007" and that "the relevant time period for determining whether the Italian Application was a printed publication is the two-week period between March 15 and March 28, 2007." (Opp. at 6.) Because patent applications in Italy are not published "in a paper or electronic journal" and are available to the public only upon request, Thermolife argues that "[a] person having ordinary skill in the art would not have discovered the Italian Application." (Id. at 7.)

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Thermolife further contends that "[e]ven if the Italian Application were found," actually obtaining a copy of the patent could theoretically be a "length[y] procedure." (Mem. at 9.) "'Depending on the number of personnel available[,] . . . the correct location of the file[,] . . . the working status of the copier machines, and the possible existence of other procedural issues, it could take several days if not weeks to receive a copy of a patent application, even if requested in person.'" (Opp. at 9 (quoting Declaration of Guido Moradei ("Moradei Decl.") ¶ 36 (citing several examples where requests took between 15 to 33 days to fulfill)).)

But these arguments hinge largely on conjecture and Thermolife completely ignores the Certification from the Director of the Italian Patent Office that the application was made accessible to the public on March 15, 2007. (See Docket No. 191-2, Cass Decl., Ex. 6 at 38.) And Defendants point out that, as both Italy and the United States are signatories to the Patent Cooperation Treaty, 35 U.S.C. § 122, "the Italian Application was publicly available by operation of law, i.e., the Patent Cooperation Treaty, Art. 53 of Legislature Decree No. 30/2005 (Industrial Property Code), and the Certification of the Director of the Italian Patent Office, as of March 15, 2007." (Reply at 8.)

ii. The Italian Patent Application Discloses the Subject Matter of the '908 Patent

Thermolife insists that "[t]he Italian Application does not disclose the subject matter of the '908 Patent" because (1) the Italian Patent Application does not "actually demonstrate a causal link between the use of D-Aspartic acid to the increase in testosterone," (Opp. at 11 (citing Wolff Decl. ¶ 12)), and (2) "[t]he prior study does not disclose that D-aspartic acid itself, D-Aspartate salts (except those neutral salts specifically listed) or D-aspartate ester compounds were ingested.'" (Id. (citing Wolff Decl. ¶ 18).) The Court has already considered—and rejected—this second argument in its discussion of claim construction. And the Court finds Thermolife's "causation" argument equally unpersuasive.

Thermolife urges that, rather than demonstrating a causal relationship between consumption of D-aspartic acid and increases in testosterone, "'the crux of the Italian Application and the prior study referenced in the Application is, at best, a method of increasing male procreativity by increasing sperm count, sperm vitality, and sperm motility.'" (Id. (citing Wolff Decl. ¶ 19).) But the Court disagrees entirely. The discussion of the prior study in the Italian Patent Application includes the following statements:

Furthermore, in the context of a study conducted on volunteers, **it was observed that ingestion of D-aspartic acid (2–4 gram daily dose) for a determined**

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> **number of days induces a statistically [significant] increase in blood testosterone concentration** and a concomitant increase in sperm count and sperm motility.
>
> In conclusion, the (unpublished) results of the study conducted on humans indicate the neutral salt of D-aspartic acid (D-aspartic acid neutralized with one of the following cations: Mg+, K+, Na+, Ca+, etc.) can be used to stimulate procreative activity in men by increasing the sperm count and sperm vitality.

(Cass Decl., Ex. 6 [Certified Translation of Italian Patent Application ("Italian Patent App.")] at 250. (emphasis added).) The language identified in bold clearly states that there is a causal link between ingestion of D-aspartic acid and an increase in testosterone levels, which in turn increases sperm count and therefore fertility.

The Court therefore concludes that the Italian Patent Application clearly anticipates both claims of the '908 Patent. Nor is this conclusion altered by the lack of expert testimony in support of Defendants' contention because, as the Federal Circuit has recognized, "[i]n many patent cases expert testimony will not be necessary because the technology will be 'easily understandable without the need for expert explanatory testimony.'" Advanced Technology Materials, Inc. v. Praxair, Inc., 228 Fed. App'x 983, 985 (Fed. Cir. 2007).

Defendants' motion for summary judgment is therefore **GRANTED** with respect to their invalidity argument.

2. DEFENDANTS ARE NOT ENTITLED TO ATTORNEY'S FEES

Section 285 provides that "courts in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285. The purpose of section 285 is to "prevent[] gross injustice where a party has demonstrated bad faith and misconduct during litigation." Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc., 549 F.3d 1381, 1388 (Fed. Cir. 2008). Thus, "[t]he trial court's discretion in awarding attorney's fees in patent cases may be invoked only upon a finding of bad faith or [i]nequitable conduct on the part of the losing party which would make it grossly unjust for the prevailing party to be left with the burden of his litigation expenses." Maurice A. Garbell, Inc. v. Boeing Co., 546 F.2d 297, 300 (9th Cir. 1976) (citations omitted).

That standard has simply not been met in this case. Although the Court has concluded that Thermolife's arguments regarding the accessibility and contents of the Italian Patent Application are ultimately unavailing, they do not rise to the level of frivolous. In fact,

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Thermolife "provided expert testimony rebutting Defendants' . . . claim that the Italian Application was published, disseminated or made accessible to the public prior to March 28, 2007." (Opp. at 1.) And the Court found Thermolife's arguments of sufficient substance that it requested additional information about the Italian Patent Application to assist it in properly disposing of this motion. The Court therefore declines to award Defendants attorney's fees in this action. The motion for summary judgment is thus **DENIED** with respect to the attorney's fees request.

III.
CONCLUSION

Accordingly, Defendants' Motion for Summary Judgment is **GRANTED** with respect to the invalidity argument. The request for attorney's fees, however, is **DENIED**. Defendants are to provide the Court with a proposed form of judgment no later than the close of business on Friday, October 11, 2013.

IT IS SO ORDERED.

JS-6

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

THERMOLIFE INTERNATIONAL, LLC,

Plaintiff,

v.

BETTER BODY SPORTS, LLC, et al.,

Defendants,

And Related Counterclaims and Consolidated Actions.

Master Case: CV12-09229 GAF (FFMx) (related/coordinated to ALL CASES)

Judge: The Honorable Gary A. Feess

JUDGMENT

On October 26, 2012, Plaintiff, Thermolife International, LLC ("Thermolife") filed its Complaint against Defendants All Star Health; Lecheek, LLC; Lone Star Distribution; Maximum Human Performance, LLP; Purus Labs, Inc.; Reaction Nutrition, LLC; Redefine Nutrition LLC; Bronson Laboratories, Inc.; Bio-Engineered Supplements and Nutrition, Inc.; Pharmafreak Holdings, Inc.; Nutrex Research, Inc.; Infinite Labs LLC; Muscle Warfare, Inc.; Allmax Nutrition, Inc.; General Nutrition Corporation; General Nutrition Centers, Inc.; GNC Corporation; Hi-Tech Pharmaceuticals, Inc.; DNA Sports Nutrition; Nutrition Zone Worldwide, Inc.; SNI, LLC; and NutraPlanet, alleging that Defendants

infringed U.S. Patent No. 8,202,908 ("the '908 patent") entitled "D-Aspartic Acid Supplement." Defendants filed their separate Answers to Plaintiff's Complaint, which included Counterclaims for (1) Declaratory Judgment of Non-Infringement; (2) Declaratory Judgment of Patent Invalidity; and (3) Inequitable Conduct.

On July 15, 2013, Defendants, All Star Health; Lecheek, LLC; Lone Star Distribution; Maximum Human Performance, LLP; Purus Labs, Inc.; Reaction Nutrition, LLC; Redefine Nutrition LLC; Bronson Laboratories, Inc.; Bio-Engineered Supplements and Nutrition, Inc.; Pharmafreak Holdings, Inc.; Nutrex Research, Inc.; Infinite Labs LLC; Muscle Warfare, Inc.; General Nutrition Corporation; General Nutrition Centers, Inc.; GNC Corporation; Hi-Tech Pharmaceuticals, Inc.; DNA Sports Nutrition; Nutrition Zone Worldwide, Inc.; SNI, LLC; and NutraPlanet (collectively, "Defendants"), filed their Motion for Summary Judgment of Invalidity of U.S. Patent No. 8,202,908 and For Attorneys' Fees.

On October 8, 2013, the Court granted Defendants' Motion for Summary Judgment and held that the '908 Patent is invalid. The Court denied Defendants' Request for Attorneys' Fees.

It is hereby ORDERED, ADJUDGED AND DECREED, based on the record in this civil action, as follows:

1. The '908 Patent is invalid;
2. Defendants' Request for Attorneys' Fees is denied;
3. Final judgment is entered in favor of Defendants;
4. Costs shall be awarded pursuant to Fed. R. Civ. P. 54(d)(1); and

/ / /

/ / /

5. The Clerk is directed to enter final judgment in accordance with the foregoing.

SO ORDERED.

Dated: October 15, 2013.

The Honorable Gary A. Feess
United States District Court Judge

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US008202908B1

(12) **United States Patent**
Arnold

(10) **Patent No.: US 8,202,908 B1**
(45) **Date of Patent: Jun. 19, 2012**

(54) **D-ASPARTIC ACID SUPPLEMENT**

(75) Inventor: **Patrick Arnold**, Champaign, IL (US)

(73) Assignee: **Thermolife International, LLC**, Phoenix, AZ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 349 days.

(21) Appl. No.: **12/383,682**

(22) Filed: **Mar. 27, 2009**

Related U.S. Application Data

(60) Provisional application No. 61/072,254, filed on Mar. 28, 2008.

(51) **Int. Cl.**

A61K 31/195	(2006.01)
A61K 9/24	(2006.01)
A61P 15/08	(2006.01)

(52) **U.S. Cl.** **514/561**; 424/464

(58) **Field of Classification Search** 514/561; 424/464

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

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5,691,377	A *	11/1997	Estienne et al.	514/557

* cited by examiner

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(57) **ABSTRACT**

The physical condition of adult male humans of all ages is improved by administering an effective amount of a D-aspartic acid compound. The administration of this compound increases their levels of testosterone, growth hormone, and/or insulin-like growth factor.

2 Claims, No Drawings

D-ASPARTIC ACID SUPPLEMENT

CROSS-REFERENCE TO RELATED APPLICATION

This application claims the benefit of U.S. Provisional Application Ser. No. 61/072,254, Mar. 28, 2008.

FIELD OF THE INVENTION

This invention relates to nutritional supplements for male humans.

BACKGROUND OF THE INVENTION

1. Aspartic Acid

Aspartic acid is an amino acid having the formula HOOC—CH_2—CH(NH_2)—COOH. Its conjugate base (formed by losing a proton) is known as aspartate. For example, sodium aspartate NaOOC—CH_2—CH(NH_2)—COOH is the sodium salt of aspartic acid. Aspartic acid and aspartate are biologically equivalent in most respects and the term "aspartic acid" is used herein to refer to both compounds.

Closely related derivatives of aspartic acid are also known. One class of derivatives, known as esters, are formed by substituting an —OR' group (where R' represents an alkyl or an aryl group) for the —OH in one of the carboxylic groups (—COOH). For example, methyl aspartate CH_3OOC—CH_2—CH(NH_2)—COOH is an ester. Another type of derivative is formed by substituting a methyl group (—CH_3) for one of the hydrogens of the amino group (—NH_2). For example, N-methyl-aspartate is a derivative having the formula HOOC—CH_2—CH(NHCH_3)—COOH. Aspartic acid, its salts such as sodium aspartate, its esters such as methyl aspartate, and other derivatives such as N-methyl-aspartate are nearly biologically equivalent in some respects and the term "aspartic acid compound" is used herein to refer to them.

In aspartic acid, the carbon atom attached to the amino group is asymmetric, i.e., it has four different groups attached to it. The presence of an asymmetric carbon makes aspartic acid a member of the class of compounds that exists in one of two optically active forms. The two forms, known as enantiomers, are mirror images of each other. They differ only in the orientation of the four groups that are attached to the asymmetric carbon.

Enantiomers have identical chemical properties except toward optically active reagents. Optically active reagents are very common in biological systems. As a result, enantiomers often have very different functions in the body.

Enantiomers are sometimes analogized to a right hand and a left hand. The two hands are mirror images of each other and are identical in most respects. However, they differ dramatically in how they fit within a right-handed glove.

One of the two enantiomers of aspartic acid is known as levorotatory aspartic acid or by the abbreviations (−)-aspartic acid, (l)-aspartic acid, or L-aspartic acid. The other enantiomer of aspartic acid is known as dextrorotary aspartic acid or by the abbreviations (+)-aspartic acid, (d)-aspartic acid, or D-aspartic acid. A mixture of equal parts of both enantiomers is known as a racemic mixture, a racemic modification, or a racemate and is designated as (±)-aspartic acid or DL-aspartic acid. The terms L-aspartic acid and D-aspartic acid are used herein for the enantiomers and DL-aspartic acid is used for the racemic mixture.

L-aspartic acid is one of the twenty-six amino acids that make up proteins. L-aspartic acid is a common nutritional supplement.

D-aspartic acid is also present in the human body, but in much smaller amounts than L-aspartic acid. As discussed in the following sections, D-aspartic acid is believed to play a role in the generation of certain hormones in male humans.

2. Male Hormones

Hormones are molecules that carry signals from one group of cells to another group of cells. Three such hormones are testosterone, growth hormone (GH), and insulin-like growth factor 1 (IGF-1).

Testosterone is the major male sex hormone in humans and other mammals. It is produced primarily in the testes. Testosterone is responsible for a wide range of beneficial effects, including increases in muscle mass, strength, and sexual performance. Growth hormone is produced in the pituitary gland and is also responsible for a wide range of beneficial effects, including increases in muscle mass. Insulin-like growth hormone 1 is produced in the liver and is further responsible for a wide range of beneficial effects.

These three hormones are at their highest levels during young adulthood when physical condition (including athletic and sexual performance) is greatest. The levels typically decline gradually as men age. Many of the undesirable effects of aging are believed to be caused by the declining levels of hormones. It is believed that increasing the levels of these three hormones improves the physical condition of adult males of all ages. However, increasing the levels by simply adding the hormones carries with it certain disadvantages.

3. The Production Of Male Hormones

The production of testosterone, growth hormone (GH), and insulin-like growth factor 1 (IGF-1) hormones in male mammals is regulated by a complex and not fully understood communication system between the hypothalamus gland located at the base of the brain, the pituitary gland (another gland located at the base of the brain), the liver, and the testes.

In the case of testosterone, its production is believed to be at least partially controlled by the following system and pathways in male humans. The hypothalamus has receptors that detect the level of testosterone in the blood. When the level becomes low, the hypothalamus generates a gonadotropin releasing hormone (GnRH) that is detected by the pituitary gland. In response to the GnRH hormone, the pituitary gland generates a luteinizing hormone (LH) that is detected by the testes. In response to the LH hormone, the testes produce testosterone.

The production of growth hormone (GH) and insulin-like growth factor 1 (IGF-1) are apparently regulated by similar systems and pathways. The hypothalamus generates a growth hormone releasing hormone (GHRH) that triggers the release of growth hormone (GH) by the pituitary. GHRH is released in pulsatile fashion and the subsequent release of GH from the pituitary is also pulsatile in nature. GH stimulates the liver to increase production and release of IGF-1. Increased levels of IGF-1 promote production of somatostatin, also known as growth hormone inhibiting hormone (GH1H), in the hypothalamus. Somatostatin acts on the hypothalamus and pituitary to decrease production of GHRH and GH. This regulatory system of GHRH, GH, IGF-1, and somatostatin is referred to as the GH/IGF-1 axis.

4. Animal Studies With D-Aspartic Acid

As previously mentioned, levels of testosterone, growth hormone, and insulin-like growth factor 1 in the blood can be increased by simply administering the hormones themselves. The levels can also be increased by adding other hormones (such as gonadotropin releasing hormone or luteinizing hor-

mone) or prohormones that trigger the body to produce the three hormones. The addition of hormones carries the potential for serious side effects and many hormones are available only with a physician's prescription.

Some recent research has indicated that certain non-hormonal compounds may also have an effect on the production of hormones in male mammals. Many experiments have been performed involving the administration of D-aspartic acid or N-methyl-D-aspartate to animals of species ranging from rats to sheep to lower primates. The administration of these two compounds has been performed by injection into the bloodstream. N-methyl-D-aspartate has also been administered orally.

For example, the administration of D-aspartic acid and N-methyl-D-aspartate has been shown to cause an increase in testosterone and growth hormone levels in the animals. Antimo D'Aniello, "D-Aspartic Acid: An Endogenous Amino Acid With An Important Neuroendocrine Role," *Brain Research Reviews*, Vol. 53, No. 2, pp. 215-234 (2007); and R. Boni et al., "Puberty In Monkeys Is Triggered By Chemical Stimulation Of The Hypothalamus," *Proceedings of the National Academy of Sciences, Vol.* 86, No. 7, pp. 2506-2510 (1989). The administration of N-methyl-D-aspartate has been shown to cause an increase in growth rate. G. Xi et al., "Growth Associated Hormones Response And Fat Metabolism Change In Finishing Pigs Fed With N-Methyl-D-Aspartate," *Asian-Australian Journal of Animal Science, Vol.* 15, No. 7, pp. 1026-1030 (2002).

As additional examples, the administration of D-aspartic acid has been shown to stimulate the release of luteinizing hormone from the pituitary, both in-vitro and in-vivo. T. Fukushima et al., "Studies On The Fate of D-Aspartic Acid In Pineal And Pituitary Glands Of Rats And Intravenous Administration," *Proc. Japan. Acad*, Vol. 74, No. B, pp. 18-23 (1998). The administration of D-aspartic acid has been shown to stimulate the release of testosterone from the testes, both in-vitro and in-vivo. Antimo D'Aniello, "Involvement Of D-Aspartic Acid In The Synthesis Of Testosterone In Rat Testes," *Life Sciences*, Vol. 59, No. 2, pp. 97-104 (1996). The administration of D-aspartic acid or N-methyl-D-aspartate has been shown to stimulate growth hormone production from the pituitary gland both in-vitro and in-vivo. Antimo D'Aniello et al., "Occurrence Of D-Aspartic Acid and N-Methyl-D-Aspartic Acid In Rat Neuroendocrine Tissues And Their Role In The Modulation Of Luteinizing Hormone And Growth Hormone Release," *The FASEB Journal*, Vol. 14, pp. 699-714 (2000).

5. Human Studies With D-Aspartic Acid

No studies have examined the effects of D-aspartic acid or N-methyl-D-aspartate on male humans. It is well known that different species of mammals often have different responses to hormones. Therefore, it is unknown whether, and to what degree, the administration of D-aspartic acid compounds in different ways and at different levels to male humans causes an increase in levels of testosterone, growth hormone, and insulin-like growth factor 1.

Accordingly, there is a demand for a method of improving the physical condition of adult male humans of all ages by increasing their levels of testosterone, growth hormone, and insulin-like growth factor 1 without the administration of hormones or prohormones.

SUMMARY OF THE INVENTION

One general object of this invention is to provide an improved method of enhancing the physical condition of adult male humans of all ages by increasing their levels of testosterone, growth hormone, and/or insulin-like growth factor 1 without the administration of hormones.

I have invented a method of improving the physical condition of an adult male human. The method comprises administering an effective amount of a D-aspartic acid compound to an adult male human.

The method of this invention improves the physical condition of adult male humans of all ages by increasing their levels of testosterone, growth hormone, and/or insulin-like growth factor 1 without the administration of hormones. The method comprises the administration of D-aspartic acid and/or its biological equivalent derivate compounds. D-aspartic acid is a chemical that is present in the human body and is generally recognized as safe.

DETAILED DESCRIPTION OF THE INVENTION

1. The Invention In General

The method of the invention comprises the administration of an effective amount of a D-aspartic acid compound to adult human males. It has been surprisingly found that the administration causes an increase in the levels of testosterone, growth hormone, and insulin-like growth factor 1. Increases in these hormones cause, in turn, an improvement in the physical condition of the males.

2. The D-Aspartic Acid Compound

Suitable D-aspartic acid compounds include D-aspartic acid, D-aspartate salts, D-aspartate esters, and other functionally equivalent derivatives such as N-methyl-D-aspartic acid. The D-aspartic acid compound is suitable in its enantiomeric form or as the racemic mixture. The preferred compound is DL-aspartic acid because of its ready availability and low cost.

3. Administration

The D-aspartic acid compound is administered in any known way that results in the compound entering the bloodstream. For example, the compound is orally ingested, injected directly into the bloodstream, administered via patches, and the like. The preferred method of administration is by oral ingestion. D-aspartic acid is well tolerated and is effectively taken into the bloodstream through the digestive tract.

The D-aspartic acid compound is conveniently ingested as a powder or is dissolved in a suitable liquid. For example, D-aspartic acid has substantial solubility in water and is well suited for addition to conventional aqueous beverages. The D-aspartic acid may have synergistic results with other common nutritional supplements, such as androst-4-ene-3,6,17-trione, marketed as 6-OXO supplement by Proviant Technologies, Inc. of Champaign, Ill.

4. Effective Amount

The D-aspartic acid compound is administered in an amount that is effective to increase the levels of testosterone, growth hormone, and/or insulin-like growth factor 1 in the recipient. In general, the D-aspartic acid compound is administered in an amount of about 1 to 100 grams per day, preferably about 1 to 20 grams per day, and most preferably about 5 to 10 grams per day, computed on the basis of equivalent molar amount of D-aspartic acid. In other words, if the DL-aspartic acid racemic modification is used, the amounts are

doubled. If a derivative is used having a molecular weight ten percent greater than that of D-aspartic acid, the amounts are increased by ten percent to provide the same equivalent molar amount.

5. Benefits

The administration of an effective amount of a D-aspartic acid compound has many beneficial effects on adult male humans. The administration causes an increase in the levels of testosterone, growth hormone, and/or insulin-like growth factor 1 in the recipient, regardless of age. The increases in these hormones, in turn, are believed to cause a large number of improvements in physical condition, including an increase in muscle mass, an increase in strength, a decrease in fat, and a reduction in various aging characteristics. Increases in these hormones are also believed to cause an improvement in sexual performance.

6. Example

The following example is illustrative only.

Example 1

This example illustrates the effects of administering D-aspartic acid to adult male humans.

A group of nine adult males ranging in age from twenty to sixty is divided into three groups of three men each. The division is made so that each group contains a similar age distribution. Blood samples are taken and the levels of testosterone, growth hormone, and insulin-like growth factor 1 are measured.

The men in the first group orally ingest 10 grams of DL-aspartic acid (which includes 5 grams of D-aspartic acid) daily for twenty-one days. The amount is divided into two equal doses, one of which is taken in the morning and one of which is taken in the evening. The men in the second and third groups follow a similar procedure except the men in the second group orally ingest 20 grams of DL-aspartic acid (which includes 10 grams of D-aspartic acid) per day and the men in the third group orally ingest 40 grams of DL-aspartic acid (which includes 20 grams of D-aspartic acid) per day. Blood samples are then retaken. The results show significant increases in the levels of the three hormones in the three groups.

I claim:

1. A method of increasing the levels of testosterone, growth hormone, and/or insulin-like growth factor 1 in an adult male human, the method comprising administering by oral ingestion a D-aspartic acid compound selected from the group consisting of D-aspartic acid, D-Aspartate salts, and D-aspartate esters to an adult male human, wherein said D-aspartic acid compound is administered in an amount and for a time sufficient to increase the levels of testosterone, growth hormone, and/or insulin-like growth factor 1.

2. The method of claim **1** wherein the D-aspartic acid compound is administered in an amount of about 1 to 20 grams of D-aspartic acid equivalent.

* * * * *

PROOF OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system on January 13, 2014. In addition, upon acceptance of this electronic filing, 6 paper copies of the foregoing will be filed with the Clerk of the Court.

I further certify that counsel of record are registered CM/ECF users and will be served by the appellate CM/ECF system as follows:

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Date: January 13, 2014

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CERTIFICATE OF COMPLIANCE

Certificate of Word Count/Compliance with Fed. R. App. P. 28(a)(11) and Rule 32(a) – Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C), the undersigned hereby certifies that the Opening Brief of Defendants-Appellants complies with the type-volume limitation of Rule 37(a)(7)(B) because this brief contains 8,036 words including both text and footnotes, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief also complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word (Version 2010) in 14 pt. font in Times New Roman.

Date: January 13, 2014

/s/ William J. Cass
William J. Cass